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09/992,167	11/06/2001	Tetsuya Ikemoto	214348	6368

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EXAMINER

REYES, HECTOR M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/29/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/992,167

Applicant(s)

IKEMOTO ET AL.

Examiner

Hector M Reyes

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-- The MAILING DATE f this communicati n appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 to 28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 to 28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 7. 6) ☐ Other:

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DETAILED ACTION

Paper Entry

Examiner acknowledges the following Papers:

- Letter, Filed on December 04, 2001 as Paper no. 2
- Information Disclosure Statement, filed on February 11, 2002, as Paper no. 3
- Copy of Foreign Papers, filed on February 11, 2002, as Paper no. 4
- Declaration, filed on February 11, 2002 as Paper no. 5
- Preliminary Amendment filed on November 6, 2002 as Paper no. 6
- Information Disclosure Statement, filed on April 1, 2003 as Paper no. 7
- Election, filed on July 7, 2003 as Paper no. 9.

Status of the claims

Claims 4, 9, 10, 12, 15, 20, 22 and 24 had been amended. Currently, claims 1 to 28 are under Examination.

Restriction Requirement

Restriction request filed as paper no. 8 is hereby vacated in view of Applicants remarks presented in Paper no. 9.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of the methyl ester derivative, is not enable for the preparation **of any other ester derivatives**.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to prepare other esters, commensurate in scope with these claims. See MPEP 2164.01

Some of the factors considered ion the present rejection are:

The Nature of the Invention

The invention is drawn to ester *compounds of Formula II. Nonetheless, the alcohol part of the claimed ester is defined as a linear or branched chain alkyl having 1 to 15 carbon atoms, which is optionally substituted by at least one substituents selected from:*

- *Phenyl group*
- *Naphtyl*
- *Cyclohexyl*
- *Cyclopentyl*
- *Norbornyl*
- *Methoxycarbonyl*
- *Ethoxycarbonyl*
- *Etc.*

While the specification provides a reaction process and conditions for the preparation of the methyl ester derivative, there is no description of a method for the preparation of the

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any other derivative and there is no evidence that the said compounds were indeed prepared.

The State of the Prior Art

Essential to the patentability of a given chemical compound is its novelty. The prior art does not disclose the preparation of non-methyl derivatives. Therefore the preparation of the said organic compounds is still a novel and synthetic challenge, moreover its further use in the any method or utility in the art. ***A patent granting the said derivatives would obscure a research area without any benefit to the public.***

The level of Predictability in the Art

While the preparation of the methyl derivative is presented in the disclosure, it is unpredictable to use the said method in order to prepared non-methyl esters, such as the corresponding derivatives having, for example different substitution aromatic or nonaromatic moieties, because different starting materials and reactions conditions would be required. Reactivity and chemical behavior and different reactions conditions are required in order to prepare different non-methyl ester compounds.

The existence of working examples

The prior art, as well as the specification of the instant invention provides no example or even a general reaction pathway directed to the preparation of the claimed non-methyl ester derivatives.

Experimentation required to make the invention

The preparation of the non-methyl ester derivatives represent a research area wherein reaction conditions and required reactants need to be determined and synthetic

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approaches would be required to be tested based on the nature of each specific reactant subjected to the specific reaction process.

The person skill in the art would need to:

- Figure out the required starting material that would provide the alcoholic part of the said esters,
- Prepare the said compounds
- Outline an esterification or any other process wherein the said compounds can be prepared, purified and its structures would be properly elucidated and
- Further use the said derivatives as intermediates in any procedure as described in the process claims of the instant invention.

See In re Wands, 8 USPQ 2d 1400 and In re Wright, 27 USPQ 2d 1510.

Claims 4 through 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of preparation wherein:

- The **methyl ester** derivative embraced by claim 1 is reacted with cyclohexane
- In the presence of titanium tetrachloride as a Lewis acid in order to provide the corresponding **methyl ester derivative** having the formula II or further
- Carry out a basic hydrolysis using aqueous sodium hydroxide to form acid V or
- Subjected it to a Pd/C reduction in order to produce the methyl ester III or
- Subject the said methyl ester having formula II both process of hydrolysis and reduction, using the same reactants in order to obtain the cyclohexyl acid IV or
- Using the said products V and III to produce the said compound IV using the same reactants

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Is not enable for:

- **The used of non-methyl ester derivatives having the formula I**
- **The used of non-methyl ester derivatives having the formula II wherein a Lewis Acid different from titanium tetrachloride is successfully used**
- **A non-basic hydrolysis nor a basic hydrolysis using any other base different from sodium hydroxide is used**
- **A non-catalytic reduction or a catalytic reduction wherein other catalysts different from Pd/C is used.**

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the said products commensurate in scope with these claims. See MPEP 2164.01

Some of the factors considered ion the present rejection are:

The breadth of the Invention

The invention is drawn to a set of different processes comprising:

- The preparation of any ester embraced by formula II by the reaction of any ester embraced by formula I with cyclohexane and any Lewis acid
- The transformation of any ester embraced by formula II via any possible reduction process in order to obtain any possible ester derivative of formula III
- The transformation of any ester embraced by formula II via any type of hydrolysis in order to obtain the acid V
- The simultaneous processes of any reduction with any hydrolysis in order to obtain the acid IV

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- The transformation of any ester embraced by formula III via any type of hydrolysis in order to obtain the acid IV
- The transformation of the acid V to the acid IV via any type of reduction.

While the specification provides enablement for:

- The preparation of the **methyl ester derivative** embraced by formula II by the reaction of methyl ester embraced by formula I with cyclohexane and titanium tetrachloride
- The transformation of methyl ester embraced by formula II via a Pd/C catalytic reduction process in order to obtain the methyl ester derivative of formula III
- The transformation of the **methyl ester derivative** embraced by formula II via basic hydrolysis using sodium hydroxide in order to obtain the acid V
- The simultaneous processes of PD/C reduction with basic sodium hydroxide in order to obtain the acid IV
- The transformation of the **methyl ester derivative** embraced by formula III via the basic hydrolysis with sodium hydroxide in order to obtain the acid IV
- The transformation of the acid V to the acid IV via the catalytic reduction with Pd/C.

There is no disclosure of the used of:

- Any non-methyl esters having the formulas I, II, or III or its preparation
- Any successful used of any other Lewis acid different from titanium tetrachloride
- Any possible reduction out of the catalytic reduction using Pd/C

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- Any other hydrolysis other than the basic medium hydrolysis using sodium hydroxide.

The State of the Prior Art

Clearly, *a patent granting the said broad processes would obscure a research area without any benefit to the public.*

The level of Predictability in the Art

It is unpredictable to carry out the claimed processes by using different reactants, reactions conditions and/or catalysts. Reactivity and chemical behavior are different for each specific set of reaction conditions and reactants. Undue experimentation would be required in order to prepare different non-methyl ester compounds and further used them under different reaction conditions, catalysts or reactants commensurate to the extend of the claimed invention.

The existence of working examples

The prior art, as well as the specification of the instant invention provides examples for processes comprising

- The preparation of the **methyl ester derivative** embraced by formula II by the reaction of methyl ester embraced by formula I with cyclohexane and titanium tetrachloride
- The transformation of methyl ester embraced by formula II via a Pd/C catalytic reduction process in order to obtain the methyl ester derivative of formula III

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- The transformation of the **methyl ester derivative** embraced by formula II via basic hydrolysis using sodium hydroxide in order to obtain the acid V
- The simultaneous processes of PD/C reduction with basic sodium hydroxide in order to obtain the acid IV
- The transformation of the **methyl ester derivative** embraced by formula III via the basic hydrolysis with sodium hydroxide in order to obtain the acid IV
- The transformation of the acid V to the acid IV via the catalytic reduction with Pd/C.

Examples in Table I, page 34, clearly indicate high variability in the yield obtained when a different Lewis base from titanium tetrachloride is used in the preparation of compound of formula II. It is shown that no all Lewis acids are indeed, conveniently used in the said process, contrary to the recitation of the claims.

Experimentation required to make the invention

The preparations or processes as claimed, represent a research area wherein reaction conditions and required reactants need to be determined and synthetic approaches would be require to be tested base on the nature of each specific reactant subjected to the specific reaction process.

The person skill in the art would need to:

- Figure out the required starting material that would provided the alcoholic part of the said esters,
- Prepared the said compounds

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- Outline an esterification or any other process wherein the said compounds can be prepared, purified and its structures would be properly elucidated.
- Once prepared, the said esters would required to be subjected to variable Lewis acids, reduction reactants and or catalysts and multiply hydrolytic processes such as acid hydrolysis, non sodium hydroxide basic hydrolysis, catalytic hydrolysis, etc.

See: In re Wands, 8 USPQ 2d 1400 In re Wright 27 USPQ 2d 1510 and Ex parte Sixto 9 USPDQ 2d 2081.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 4-7, 10-17 and 20 to 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 2, 4, 5, 10, 11, 13, 16, 20, 21, 22, 23, 24 and 25 the definition of the R' is indefinite. The said definition contains two phrases with alternatives moieties and it is unclear the part of the molecule wherein the second of those phrases recites "which is optionally substituted by at least one substituent selected from the group" is directed. It is indefinite where in the structure of the molecule the said optional moieties are intended to be present.

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In claims 4, 5, 6, 11, 20, 21, 22, 23, 24 and 25 it is unclear if the variables R and R' are different or are the same. If the said variables are different, how the transformation of the said variable is achieved?

In claims 4, 7, 20, 22 and 24, the phrase **in the presence of a Lewis Acid** is indefinite because it is unclear which Lewis acid may or not be successfully used in the claimed process.

In claim 10,14, the phrase **reducing a compound of claim 1** is indefinite because the reducing agent is not identify nor it is clear if the reduction is a catalytic reduction or is a non-catalytic reduction.

In claim 12, the phrase hydrolyzing a compound of claim 1 is indefinite. How the said hydrolysis is done? What is the hydrolysis type? What reagents are needed?

In claim 15, 17, the phrase **hydrolysis and reduction** and in claims 18, 19, 24, 26, 27 and 28, the phrases **hydrolysis after reduction** or vice versa are indefinite because the limitations of the said processes are not indicated. For instance, the reducing agent is not identified nor it is clear if the reduction is a catalytic reduction or is a non-catalytic reduction.

How the said hydrolysis is done? What is the hydrolysis type? What reagents are needed?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 3 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Senanayake et al, WO 0027786.

Senanayake discloses the acid of formula V as intermediate in the synthesis of cycloalkylphenylglycolic acids. See page 7. Indeed, the said acid V is reduced using Pd/ C in order to prepare the acid of formula III, see experimental examples.

CONCLUSION

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Clerici et al, Tetrahedron, vol. 42 (2) pp 561-572 (1986) disclosing the reaction of methyl phenyl glyoxylate with titanium derivatives in order to afford pinacols. Some of the ketones used had also alkene functionality. Chemoselectivity is discussed. Any inquiry concerning this communication should be directed to Hector M. Reyes whose telephone number is (703) 605-1153. The examiner can normally be reached on Monday to Friday from 8 am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner 's supervisor, Allan Rotman, whose telephone number, is (703) 308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or for regular communication and (703) 308-4242 for After Final communications.


Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Héctor M. Reyes PhD, JD

June 20, 2003


D. MARGARET SEAMAN
PRIMARY EXAMINER